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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/554,996	05/24/2000	Mark T. Keating	HYDR-P01-002	4041

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EXAMINER	
CHEN, SHIN LIN	
ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 11/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/554,996	KEATING ET AL.	
	Examiner	Art Unit	
	Shin-Lin Chen	1632	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 18 October 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: *1-4,6-14,48-50,56-63,65 and 67-69*.

   Claim(s) objected to: *None*.

   Claim(s) rejected: *22-24,26-33 and 35*.

   Claim(s) withdrawn from consideration: *5 and 25*.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Shin-Lin Chen
Primary Examiner
Art Unit: 1632

Continuation of 3. Applicant's reply has overcome the following rejection(s): 35 U.S.C. 112 first paragraph rejection of claims 1-4, 6-14, 48-50, 56-63, 65 and 67-69.

Continuation of 5. does NOT place the application in condition for allowance because: Applicants cite declaration by Dr. Dean Li and amend claims to read on a pharmaceutical composition that provides an elastin-based composition comprising a polypeptide comprising or consisting essentially of an amino acid at least 95% identical to SEQ ID No. 3, or a bioactive fragment of SEQ ID No. 3 or a peptide fragment consisting essentially of 6 or 7 repeats of the sequence of SEQ ID No. 1. Applicants argue thar the amendment reflect the suggestions of examiner in the previous Official action and further incorporate the subject matter supported by Dr. Li's declaration (amendment, p. 10-11). This is not found persuasive because of the reasons of record regarding claims 22-24, 26-33 and 35. The claim read on using the pharmaceutical composition to prevent or treat restenosis as claimed via various administration routes in vivo. The claims are not limited to a particular administration route. The specification only teaches delivery of a peptide having the sequence of SEQ ID No. 2, which has 7 repeats of hexamer derived from human elastin, or elastin tube to coronary artery by direct administration of said peptide or elastin tube into the coronary artery via the use of intravescular stent and balloon catheter to prevent vascular restenosis. The declaration by Dr. Dean Li only enables the inhibition of restenosis by administering a stent coated with elastin-based composition comprising 6 repeats of VGVAPG directely into rabbit carotid arteries. The specification fails to provide adequate guidance and evidence that the claimed polypeptides could be used for prophylaxis or treatment of restenosis so as to provide therapeutic effect in treating or preventing restenosis via various administration routes in vivo. Administration route of a pharmaceutical composition plays an important role in the efficiency of said composition in vivo. The type of administration route determines how the claimed elastin-based composition reaches its targeted site in vivo. The location of administration, the amount and stability of the polypeptides or peptides in vivo, and its compartmentalization within the cell are all important factors in determining whether sufficient polypeptides or peptides can reach their target site so as to provide therapeutic effects for preventing or treating restenosis in vivo. thus, claims 22-24, 26-33 and 35 remain rejected under 35 U.S.C. 112 first paragraph.